REMARKS

This Amendment is responsive to the Office Action dated December 28, 2006. Applicant has amended claims 33 and 42, and canceled claim 39. Claims 33-38, 40-49 and 55-56 are pending.

Objection to the Specification

The Office Action objected to the specification as failing to provide proper antecedent basis for the second interval being 60 ms, as recited in claim 40. Applicant respectfully disagrees with this finding. Nonetheless, in the interest of advancing prosecution of the present application, Applicant has amended independent claim 33, from which claim 40 depends. Applicant submits that the specification provides proper antecedent basis the claims as amended, and respectfully requests that the objection to the Specification be withdrawn.

Claim Rejections Under 35 U.S.C. § 103

The Office Action rejected, under 35 U.S.C. § 103(a):

(a) claims 33-34, 37-40 and 55 as being unpatentable over Lebel et al. (US 6,585,644, hereinafter "Lebel") in view of Smith (US 5,108,889);

(b) claim 35 as being unpatentable over Lebel in view of Smith as applied to claims 33, 34, 37-40 and 55 above, and further in view of Cozette (US 5,063,081);

(c) claim 36 as being unpatentable over Lebel in view of Smith as applied to claims 33, 34, 37-40 and 55 above, and further in view of Miller (US 4,748,562);

(d) claims 41 and 42 as being unpatentable over Lebel in view of Smith as applied to claims 33, 34, 37-40 and 55 above, and further in view of Schulman et al. (US 5,497,772, hereinafter "Schulman");

(e) claims 43 and 45-49 as being unpatentable over Petty (US 4,503,859) in view of Lebel and Smith;

(f) claim 44 as being unpatentable over Petty in view of Lebel and Smith as applied to claims 43 and 45-49 above, and further in view of Cozette; and

(g) claim 56 as being unpatentable over Petty in view of Lebel and Smith as applied to claims 43 and 45-49 above, and further in view of Miller.

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Applicant respectfully traverses these rejections to the extent such rejections are considered applicable to the amended claims. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Lebel discloses a system that includes an "implanted medical device (e.g. infusion pump) and an external device [that] communicate with one another via telemetry messages that are receivable only during windows or listening periods."[1] In this manner, the Lebel disclosure may minimize power consumption of the medical device through reduced telemetry usage. The Lebel system may also include a sensor that "may be used to detect various physiological parameters."[2]

The Smith system is directed to an assay that determines an analyte "by a change in at least one property of the metal caused by such interaction"[3] between a ligand having a mercury label and a metal. In this manner, Smith describes a "medical whole blood and other liquid analyzing system" for use "at bedside... at home... and disposable after a single use."[4] The Smith system is also described as being used in assay instruments, assay sensors, instrumentation, and related methods.

Claims 33-42 and 55

Independent claim 33 requires a casing adapted to be implanted and secured within the body of a patient in a location wherein the surrounding environment provides the at least one physiological parameter indicative of gastroesophageal reflux and a sensor, positioned within the casing, wherein the sensor is adapted to measure the at least one physiological parameter indicative of gastroesophageal reflux. The implantable device recited by claim 33 also includes a transmitter, positioned within the casing, wherein the transmitter is adapted to send a parameter signal indicative of the measured at least one physiological parameter to a receiver located outside of the body of the patient and a power source, positioned within the casing, that provides power to the sensor and the transmitter. In addition, as amended, claim 33 requires a processor, positioned within the casing, that periodically induces the sensor to obtain the at least one

[1] Lebel et al., Abstract.
[2] Lebel et al., Col. 9, ll. 39-40.
[3] Smith et al., Abstract.
[4] Smith et al., Col. 4, ll. 51-61.

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physiological parameter and periodically induces the transmitter to transmit a parameter signal indicative of the at least one physiological parameter, wherein the processor enables delivery of power from the power source to the sensor only during a first time interval during each measurement cycle when the sensor is sensing the at least one physiological parameter and wherein the processor enables delivery of power from the power source to the transmitter only during a second time interval during each measurement cycle when the transmitter is transmitting the parameter signal so that consumption of power by the sensor and the transmitter is reduced during intervals of each cycle other than the first and second interval respectively. Lebel in view of Smith fails to teach or suggest each of the elements of independent claim 33.

In support of the rejection of claim 33, the Office Action characterized Lebel as showing a device with a casing 6 adapted to be implanted and secured within a patient's body in an area where the environment has a parameter, pH, indicative of reflux, a pH sensor in the casing, transmitter 76 in the casing, adapted to send a signal to an external receiver, a power source 74 in the casing, and a processor in the casing that supplies power to the transmitter only during certain times to minimize power consumption. The Office Action acknowledged that Lebel fails to disclose supplying power periodically to the sensor. The Office Action cited Smith, however, as teaching that in order to further minimize power consumption, the sensor may only be energized for small periods of time. On this basis, the Office Action concluded that it would have been obvious to modify Lebel to periodically enable the sensor to further conserve power.

Applicant disagrees with the conclusion of obviousness for a number of reasons. For example, housing 6 of the Lebel system is not adapted to be implanted and secured within the body of a patient in a location wherein the surrounding environment provides the at least one physiological parameter indicative of gastroesophageal reflux, as required by claim 33. Furthermore, even if Lebel was modified in view of Smith, the resulting combination would still fail to duplicate the elements of claim 33, as amended.

Nowhere does Lebel describe a casing adapted to be implanted and secured within the body of a patient in a location wherein the surrounding environment provides the at least one physiological parameter indicative of gastroesophageal reflux. Lebel discloses "infusion pumps may dispense insulin, analgesics, neurological drugs, drugs for treating AIDS, drugs for treating

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chronic ailments or acute ailments."[5] In addition, Lebel teaches: "[s]ensors may be used to detect various physiological parameters such as hormone levels, insulin, pH, oxygen, other blood chemical constituent levels, and the like."[6]

Because pH may be sensed in a variety of locations or fluids for a variety of reasons, the mere mention of pH sensing in Lebel is not a disclosure or suggestion of a physiological parameter indicative of gastroesophageal reflux. Lebel does not even mention gastroesophageal reflux. Moreover, Lebel does not suggest that the implant casing 6, as opposed to a lead carrying a sensor or the like, is implanted in a location wherein the surrounding environment provides the pH to be measured. Thus, Lebel does not disclose or suggest a casing, which houses sensor, transmitter and a processor, implanted in a location wherein the surrounding environment provides the at least one physiological parameter indicative of gastroesophageal reflux, as required by claim 33.

In addition, even if the Lebel system was modified according to the Smith disclosure, the resulting combination fails to duplicate the elements of claim 33. According to the Office Action, Lebel teaches restricting when power is delivered to a transmitter, and Smith teaches restricting when power is delivered to a sensor. However, neither reference teaches any relationship between delivery of power to a sensor and delivery of power to a transmitter. Thus, even the combined teaching of Lebel and Smith fails to teach delivering power to a sensor and transmitter only during respective first and second intervals, as required by amended independent claim 33.

With respect to dependent claims 38 and 40, the Office Action stated that the recited interval lengths would have been a mere matter of design choice for a person of ordinary skill. Applicant respectfully disagrees. Moreover, the mere assertion of "design choice" does not meet the evidentiary standard for a prima facie case of obviousness, as stated in Federal Circuit precedent.[7] The Office Action does not even provide evidence substantiating the existence of devices using the intervals recited in claims 38 and 40 at the time of Applicant's invention, much less evidence of a motivation to modify the Lebel device to utilize the recited intervals.

[5] Lebel et al., Col. 9, ll. 36-39.
[6] Lebel et al., Col. 9, ll. 39-42.
[7] *E.g.*, *In re Lee* 61 USPQ2d 1430 (CAFC 2002).

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Further, the applied references fail to disclose or suggest a processor within a casing implanted within the patient that applies calibration data such that a receiver external to the patient receives a calibrated signal, as required by amended claim 42. In rejecting claim 42, the Office Action cited Schulman for its teaching of a memory within an implantable sensor that stores calibration data. However, Schulman does not teach that a processor within the implantable sensor applies calibration data, as required by claim 42. Instead, Schulman teaches that the sensor transmits the calibration data to external device when coupled thereto so that the external device may apply the calibration data when it receives glucose sensor data from the sensor.[8]

Also, the applied references fail to teach or suggest a casing that houses a sensor, transmitter and processor adapted to be implanted within an esophagus. The Office Action stated that the Lebel casing 6 can be immobilized in the esophagus. However, this statement does not appear to be based on any teaching in Lebel. Thus, the rejection of claim 55 appears to be based on hindsight and/or conjecture, which is improper.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 33-42 and 55 under 35 U.S.C. § 103(a). Withdrawal of these rejections is requested.

Claims 43-49 and 56

Independent claim 43 requires providing power to a sensor circuit for a first time interval so as to obtain a parameter measurement indicative of gastroesophageal reflux and ceasing providing power to the sensor circuit following the first time interval. Claim 43 also includes providing power to a transmitter circuit during a second time interval, following the first time interval, so that a parameter signal indicative of the parameter measurement obtained by the sensor circuit can be transmitted to a receiver located outside of the body of the patient, and ceasing providing power to the transmitter circuit following the second time interval. Petty in view of Label and Smith fails to teach or suggest the elements of claim 43.

[8] Schulman, Col. 6, ll. 17-39.

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As discussed above, Lebel and Smith fail to disclose or suggest any relationship between delivery of power to a sensor and delivery of power to a transmitter. Petty provides no teaching that overcomes this deficiency of Lebel and Smith. Thus, the applied references would fail to suggest the requirements of independent claim 43.

Furthermore, the evidentiary record is inadequate to maintain the rejection of claims 45, 48 and 49 for the reasons stated above with respect to claims 38 and 40. The Office Action cites no teaching of the recited intervals in a prior art reference.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 43-49 and 56 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

April 30, 2007

By:

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,298	10/16/2003	John T. Kilcoyne	1065-012US04	7921

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EXAMINER	
NASSER, ROBERT L	
ART UNIT	PAPER NUMBER
3735	

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SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary

Application No.	Applicant(s)	
10/687,298	KILCOYNE ET AL.	
Examiner	**Art Unit**	
Robert L. Nasser	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/13/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-49,55 and 56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-49,55 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/11/04 and 8/1/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

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The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not support the second interval being 60 ms, as the specification states that the correction 338, message formation 340, and transmission 342 states together take approximately 60 ms. Correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33-34, 37-40, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al 6585644 in view of Smith 5108889. Lebel shows a device with a casing 6 adapted to be implanted and secured within a patient's body in an area where the environment has a parameter, pH, indicative of reflux, a pH sensor in the casing (see column 9, lines 40 and 41), transmitter 76 in the casing, adapted to send a glucose signal to an external receiver, a power source 74 in the casing, and a processor in the casing that supplies power to the transmitter only during certain times to minimize power consumption (see discussion of listening periods throughout). It does not supply power periodically tot he sensor. However, Smith teaches that in order to further minimize power consumption, the sensor may only be energized for small periods of time (see column 50, lines 38-45). Hence, it would have been obvious to modify Lebel to periodically enable the sensor, to further conserve power. Claim 37 is rejected in that the transmitter is rf and transmits a digital signal. Claims 38 and 40 are rejected in that

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the exact time each of the transmitter and sensor are energized would have been a mere matter of design choice for one skilled in the art. Claim 39 is rejected in that the combination would have a sensing period and a transmitting period, where only the sensor or transmitter are enabled. Claim 55 is rejected in that the casing can be immobilized in the esophagus.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al in view of Smith as applied to claims 33, 34, 37-40, and 55 above, and further in view of Cozette 5063081. Cozette teaches that a ISFET/amplifer is a known pH sensor. Hence, it would have been obvious to modify the above combination to use such a sensing system, as it is merely the substitution of one known sensor for another.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al in view of Smith as applied to claims 33, 34, 37-40, and 55 above, and further in view of Miller 4748562. Miller teaches that a antimony electrode/amplifer is a known pH sensor. Hence, it would have been obvious to modify the above combination to use such a sensing system, as it is merely the substitution of one known sensor for another.

Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al in view of Smith as applied to claims 33, 34, 37-40, and 55 above, and further in view of Schulman et al 5497772. Schulman teaches storing calibration data with a sensor to ensure proper calibration of the device. Hence, it would have been obvious to modify the combination to use such a memory, to ensure accurate measurements.

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Claims 43, 45-49 are rejected under Petty 4503859 in view of Lebel et al and Smith. Petty shows an implantable pH sensor for measuring pH having a telemetry link to a data receiver (see column 4, line 5). Lebel and Smith teach respectively, that to conserve power, the transmitter and sensor should only be activated for a portion of the cycle. Hence, it would have been obvious to modify Petty to use such a power scheme, to conserve energy. Claims 45, 48, and 49 are rejected in that the exact time each of the transmitter and sensor are energized would have been a mere matter of design choice for one skilled in the art. Claim 47 is rejected in that the examiner takes official notice that rf is a well known telemetry medium.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Petty in view of Lebel et al and Smith as applied to claims 43 and 45-49 above, and further in view of Cozette 5063081. Cozette teaches that a ISFET/amplifer is a known pH sensor. Hence, it would have been obvious to modify the above combination to use such a sensing system, as it is merely the substitution of one known sensor for another.

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Petty in view of Lebel et al and as applied to claims 43 and 45-49 above, and further in view of Miller 4748562. Miller teaches that a antimony electrode/amplifer is a known pH sensor. Hence, it would have been obvious to modify the above combination to use such a sensing system, as it is merely the substitution of one known sensor for another.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Gross et al 5800420 shows a very similar system for measuring glucose, where the sensor and transmitter are periodically energized. It does not measure pH or a parameter indicative of reflux.

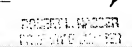
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert L. Nasser
Primary Examiner ,
Art Unit 3735

RLN



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